REMARKS

I. Response to rejections of claims 9 and 19 under 35 U.S.C. 112, second paragraph.

The Office Action rejected claims 9 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has since amended claims 9 and 19 and made the rejection moot. Hence, Applicant respectfully requests that the rejection of claims 9 and 19 be withdrawn.

II. Response to rejections under 35 U.S.C. 102.

A. Response to rejections of claims 1, 3-5, 9-11 and 13-15 under 35 U.S.C. 103(b)

The Office Action rejected claims 1, 3-5, 9-11, and 13-15 under 35 U.S.C. 102 (b) as being anticipated by Garewal et al. The Office Action asserted that Garewal et al. teach performing the method using normal gastric cardia (negative control) and gastric cardia biopsies showing gastric intestinal metaplasia. The Office Action stated that "gastric" is defined as "relating to the stomach" and "cardia" as the area of the stomach close to the esophageal opening according to Stedman's Medical Dictionary. The Office Action then concluded that the gastric cardia biopsies in Garewal et al. are by definition stomach tissues encompassed within the gastric samples of Applicant's invention.

Applicant has since amended claims 1 and 11 by adding a limitation that excludes the gastric cardia from the gastric issue. To the extent that the rejection may be held to apply to the claims as amended, Applicant respectfully traverse. On one hand, "gastric cardia," in Stedman's Medical Dictionary, is defined as " Pars cardiaca ventriculi" which is further defined as "the area of the stomach close to the espophageal opening (cardiac opening) which contains the cardiac glands. On the other hand, it is well documented that the stomach (gaster, ventriculus) is divided into several distinct regions according to the character of the glands." *See*, Amenta P. & Amenta

P., Histology: From Normal Microanatomy to Pathology, Ch. 12, P. 350. The regions of a stomach include: 1) cardia or cardiac region (pars cardiaca), a small region about 25 mm long (ranging from 5mm to 40 mm) starting at the stomach entrance (ostium cardiacum), 2) fundus (fudus gastricus, also fundus ventricularis), the dome-shaped portion to the left of the cardia (usually filled with air), 3) the body (corpus gastricum, corpus ventricularis), comprising the bulbous two-thirds of the stomach, 4) gastric canal (canalis gastricus, canalis ventricularis) or antrum, an intermediate narrow region leading to the pyloris, and 5) the pars pylorica, about 5 cm long, which narrows down pyloric antrum to a narrow canal (pyloric canal) directed to the first segment of the small intestine, the duodenum. *See, supra.* In short, gastric cardia is a distinct part of the stomach close to the espophageal opening (cardiac opening) containing the cardiac glands. In other words, gastric cardia patently differs from other parts of the stomach such as fundus ventricularis, corpus ventricularis, canalis ventricularis, and the pars pylorica.

In order for a cited reference to anticipate a claimed invention, the cited reference must teach each and every element of the claim. It is true that Garewal et al. teach the staining of gastric cardia biopsies using Das-1 monoclonal antibody. Yet, it is also true that Garewal et al. teach that the Das-1 monoclonal antibody does not react with normal esophageal mucosa, gastroesophageal junction, different parts of the stomach nor small intestine. It follows that when the claimed invention is directed to a gastric tissue other than the gastric cardia, as amended herein, the claimed invention is no longer anticipated by Garewal et al. Accordingly, Applicant respectfully requests that the rejection of claims 1, 3-5, 9-11 and 13-15 under 35 U.S.C. 103(b) be withdrawn.

B. Response to rejection of claims 1, 3-5, 9-11 and 13-15 based on inherency.

The Office Action rejected claims 1, 3-5, 9-11 and 13-15 as being inherently present in the prior art. Specifically, the Office Action reasoned that Garewal et al. teaches contacting gastric tissue with the same monoclonal antibody (Das-1) as that of the present invention. While conceding that Applicant's claims recites a newly discovered property of the prior art antibody, the Office Action nevertheless asserted that the claiming of a new property which is inherently present in the prior art does not make a claim patentable. Applicant respectfully traverses.

It is a general rule that the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 195 USPQ 430, 433 (C.C.P.A. 1977). However, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 28 U.SPQ2d 1955, 1957 (Fed. Cir. 1993). To establish inherency, it must be made clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skills. In re Robertson, 49 USPQ2d 1949 (Fed. Cir. 1999). The Robertson court particularly ruled that inherency may not be established by probabilities or possibilities and that mere fact that a certain thing may result from a given set of circumstances is not sufficient. Supra, at 1951.

Applicant reminds that Garewal et al. do not teach contacting gastric tissues in general with the monoclonal antibody. Garewal et al. merely teach contacting gastric cardia with the monoclonal antibody for detecting incomplete type gastric intestinal metaplasia. That gastric cardia can be contacted with the monoclonal antibody does not necessarily result in that gastric tissues other than gastric cardia can be contacted with the monoclonal antibody. It is merely a

possibility that gastric tissues other than gastric cardia may be contacted with the antibody for diagnosing human colonic type gastric intestinal metaplasia. Contrary to the teaching of the instant application, Garewal et al suggests that other gastric tissues would not react with the monoclonal antibody DAS-1 since it did not react with different parts of the stomach (gastric tissues).

In light of Rijckaert and Robertson, inherency can not be established by the fact that the gastric tissues other than gastric cardia may be contacted with the monoclonal antibody, nor by possibilities of such fact, much less by the teaching against such possibilities. Accordingly, Applicant respectfully requests that the rejection based on inherency by withdrawn.

C. Response to rejection of claims 1-5 and 9-15 under U.S.C. 102 (a).

The Office Action rejected claims 1-5 and 9-15 under 35 U.S.C. 102(a) as being anticipated by Griffel et al. The rejection was predicated on the following portion of Griffel's publication, as cited by the Office Action:

"... MAbDAS-1 has been shown to react with only approximately 25% of cases of gastric intestinal metaplasia, which is approximately the percentage that is thought to be of the incomplete or colonic type. This suggested that this antibody does not react with all intestinal metaplasia, but only that of the colonic type."

Page 41, Griffel et al. The Office Action further asserted that the fact that Griffel et al. teach that the monoclonal antibody can also be used to distinguish the terminal stage of progression of tissue to Barrett's Esophagus does not negate the teaching that reactivity of gastric tissue with the monoclonal antibody is diagnostic of human colonic type gastric intestinal metaplasia.

To the extent that the rejection can be held to apply to claims as amended, Applicant respectfully traverses. Applicant's disclosure of his or her own work within a year before the application filing date cannot be used against him or her under 35 U.S.C. 102(a). In re Katz, 215 USPQ 14 (C.C.P.A. 1982). Where the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavits made out by other authors establishing that the relevant portions of the publication originated with, or were obtained, from applicant. Ex parte Hirschler, 110 USPQ 384 (Bd. App. 1952).

Applicant points out that the publication cited in the Office Action were co-authored by Louis Griffel, Peter Amenta, and Kiron Das, where Applicant was one of the co-authors. Applicant submits a 37 C.F.R. 1.132 affidavit attached herein to show that the portion of the publication cited by the Office Action were originated with Applicant. Accordingly, Applicant respectfully requests that Griffel et al. be removed as a prior art reference and the rejection of claims 1-5 and 9-15 under 35 U.S.C. 102(a) be withdrawn.

III. Response to rejections under 35 U.S.C. 103

A. Response to the rejection of claims 1-6, 8-16, and 18-20.

The Office Action rejected claims 1-6, 8-16 and 18-20 under U.S.C. 103(a) as being unpatentable over either Garewal et al. in view of Badve et al., or Griffel et al., as applied to claims 1-5 and 9-15 above, and in further view of Pantuck et al., Babaev et al., and Petersen et al. The Office Action asserted that Garewal et al. teach that DAS-1 reacts with a subset of incomplete gastric intestinal metaplasia and Badve et al. teach that DAS-1 recognizes a protein unique to the colonic epithelium. The Office Action further asserted that the prior art points

directly to and teaches a reasonable expectation of success using DAS-1 to diagnose colonic type gastric intestinal metaplasia.

To the extent that the rejection can be held to apply to claims as amended, Applicant respectfully traverses. One of the requirements for establishing a 35 U.S.C. 103(a) rejection is that the prior art reference (or references when combined) must teach or suggested all the claim limitations. M.P.E.P. 2143. Applicant's claimed invention is directed to contacting a gastric tissue with the DAS-1 wherein the gastric tissue is not a gastric cardia. However, Garewal et al. teaches contacting gastric cardia as a part of Barret's Esophagus with the DAS-1 monoclonal antibody. Badve et al. teach contacting colonic epithelium with DAS-1. Griffel et al. are not a prior art reference as discussed in Section (II)(C) of this response. Since colonic epithelium is not the gastric tissue in the claimed invention, nor is gastric cardia, Applicant finds no reason that the prior art references, by themselves or in combination, can teach or suggest all the claimed limitations in the Applicant's application.

Applicant further contends that one skilled in the art would not have had a reasonable expectation of success because the prior arts teaches away from the notion that DAS-1 would be reactive to gastric tissues which are not gastric cardia. Applicant notices that Garewal et al. teach that DAS-1 is reactive to a gastric cardia showing intestinal metaplasia. However, nowhere do Garewal et al. teach or suggest contacting a gastric tissue that is not gastric cardia with DAS-1 for diagnosing colonic type intestinal metaphasia. To the contrary, Garewal et al. teach that MAbDAS-1 does not react with different parts of the stomach or small intestine. This teaching, along with the teaching that DAS-1 reacts only with colonic epithelium, would naturally discourage one of ordinary skill in the art to reach a reasonable expectation of success in contacting DAS-1 with a gastric tissue sample that is not gastric cardia.

In light of the foregoing, Applicant contends that prior art references, either alone or in combination, do not teach or suggest all the elements of the claimed invention, Applicant further contends that prior art references actually teach away from the claimed invention. Therefore, Applicant respectfully requests that the rejection be withdrawn.

B. Response to the rejection of claims 7 and 17.

The Office Action rejected claims 7 and 17 under U.S.C. 103(a) as being unpatentable over wither Garewal et al. in view of Badve et al., or Griffel et al. in view of Pantuck et al., Babaev et al., and Petersen et al.

To the extent that the rejection can be held to applied to claims as amended, Applicant respectfully traverse. For the same reasons as presented in Section (III)(A) of this response, applicant respectfully requests that the rejection be withdrawn.

V. Conclusion:

In light of the foregoing, Applicant submits that all claims are in condition for allowance. Applicant respectfully requests the Examiner to issue a notice of allowance.

Respectfully submitted,
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Marked Up Version to Show Amendments

1. [Twice Amended] An in vitro immunoassay method for diagnosing human colonic type gastric intestinal metaplasia which comprises the steps of:

(a) contacting a gastric tissue sample of a subject suspected of having human colonic type gastric intestinal metaplasia cells with the monoclonal antibody DAS-1, or a fragment thereof, which monoclonal antibody is produced by the hybridoma deposited under ATCC accession number HB 9397 and which reacts with human gastric intestinal metaplasia antigen, [wherein the gastric tissue is not a gastric cardia]; and

(b) detecting immunoreactivity between the gastric tissue and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human colonic type gastric intestinal metaplasia.

9. [Twice Amended] The method according to claim 1, further comprising the step of performing a negative control assay on a negative control sample to detect cells of human colonic type gastric intestinal metaplasia present in the negative control sample [in the gastric tissue sample of the subject suspected of having human colonic type gastric intestinal metaplasia] and comparing results of the assay in (b) [gastric tissue sample] with the results of the negative control assay[sample], wherein the presence of human colonic type gastric intestinal metaplasia cells in the assay in (b) above [gastric tissue sample over] the presence [absence] of human colonic type gastric intestinal metaplasia cells in the negative control assay [sample] indicates a positive diagnosis of human colonic type gastric intestinal metaplasia.

11. [Twice Amended] An in vitro immunoassay method for screening for human colonic type gastric intestinal metaplasia, wherein reactivity with DAS-1 is indicative of a predisposition for gastric carcinoma, which comprises the steps of:

(a) contacting a gastric tissue sample of a subject suspected of having human colonic type gastric intestinal metaplasia cells with the monoclonal antibody DAS-1, or a fragment thereof, which monoclonal antibody is produced by the hybridoma deposited under ATCC accession number HB 9397 and which reacts with human gastric intestinal metaplasia antigen, [wherein the gastric tissue is not a gastric cardia];; and

(b) detecting immunoreactivity between the gastric tissue and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human colonic type gastric intestinal metaplasia.

19. [Twice Amended]The method according to claim 16, further comprising the step of performing a negative control assay on a negative control sample to detect cells of human colonic type gastric intestinal metaplasia present in the negative control sample [in the gastric tissue sample of the subject suspected of having human colonic type gastric intestinal metaplasia] and comparing results of the assay in (b) [gastric tissue sample] with the results of the negative control assay[sample], wherein the presence of human colonic type gastric intestinal metaplasia cells in the assay in (b) above [gastric tissue sample over] the presence [absence] of human colonic type gastric intestinal metaplasia cells in the negative control assay [sample] indicates a positive diagnosis of human colonic type gastric intestinal metaplasia.